

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### Effect of the educational intervention based on the health belief model on physical puberty health of girl students of 9th grade in public schools

#### Protocol summary

##### Study aim

Determine the Impact of educational intervention based on the health belief model on physical puberty health behavior of girl students of 9th grade in public schools in Rasht city, in 2018

##### Design

Randomized controlled trial, the intervention group (49) and control group (49), with parallel groups, not blind, random cluster.

##### Settings and conduct

Four schools are randomly selected from the list of schools in Rasht and randomly assigned to the control and test groups. To prevent the transmission of control and test information, the selected schools are randomly selected at a distance. From each school, a class is selected in the form of a draw. According to the research criteria, In total, 98 female students of the 9th grade will be included in the test and control groups.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: Employment at the ninth grade, having menarche experience (first menstruation). Exit criteria: physical and mental disability, not having satisfaction to participate in the study.

##### Intervention groups

Educational intervention program based on the health belief model will be carried out to improve the physical puberty health behavior of girl students. Before conducting the training classes, at first assessment will be based on the health belief model (pre-test) for the intervention and control group. Then, for intervention groups, 16 training sessions will be held between 45-60 minutes (for 4 subgroups of 12 people) and one month after the intervention, a reassessment based on the health belief model (post-test) will be performed for both intervention and control groups. In order to follow the ethical point of view, after the post-test, the training program for the control group is also conducted in two sessions.

##### Main outcome variables

Puberty health behavior

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181014041337N1**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **prospective**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

##### Registration date

2018-12-21, 1397/09/30

##### Registrant information

##### Name

Zahra Aghaee Kenari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3332 5058

##### Email address

aghaeezahra@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-05, 1397/10/15

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Effect of the educational intervention based on the health belief model on physical puberty health of girl students of 9th grade in public schools

**Public title**  
Study of The effect of educational intervention based on health belief model on health-puberty girls

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Employment at the ninth grade Having menarche experience (first menstruation)  
**Exclusion criteria:**  
Having physical and mental disabilities not having satisfaction to participate in the study

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **98**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization is clustered. At first, each class is given from 1 to 4 numbers and using random numbers table, two of the 1-4 randomly selected and assigned to the intervention classes.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

##### Street address

Office center of Guilan University of Medical Sciences, Parastar Street, Rasht, IRAN

##### City

Rasht

**Province**  
Guilan  
**Postal code**  
4157679466  
**Approval date**  
2018-09-22, 1397/06/31  
**Ethics committee reference number**  
IR.Gums.REC.1397.240

## Health conditions studied

### 1

#### Description of health condition studied

Puberty health behavior in student girls

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Puberty health behavior

#### Timepoint

Before the intervention and one month after the intervention.

#### Method of measurement

Validated questionnaire of health belief model constructs.

## Secondary outcomes

### 1

#### Description

knowledge

#### Timepoint

Before the intervention and one month after the intervention

#### Method of measurement

Validated questionnaire of health belief model constructs

## Intervention groups

### 1

#### Description

Intervention group: educational intervention is organized in the form of holding educational classes based on the health belief model, in order to increase the awareness of puberty health behavior which includes 16 training sessions of 45-60 minutes for 4 subgroups of 12 people. Training is based on educational methods such as lectures, group discussions, role play, rewarding, and educational tools such as tracks, pamphlets, and powerpoint slides. Evaluation is based on the health belief model before the intervention and one month after the intervention.

#### Category

Behavior

## 2

### Description

Control group: This group will not receive educational intervention and assessment will be done based on the health belief model in this group before and one month after the intervention. In order to follow the ethical point of view, after the post-test, the training program for the control group is also performed in two sessions.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Education of Guilan Province

##### Full name of responsible person

Dr. Nader Jahan Ara

##### Street address

Farhang Square, Rasht, Gilan Province

##### City

Rasht

##### Province

Guilan

##### Postal code

4157679466

##### Phone

+98 13 3332 9082

##### Email

medu@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Dr Shadman Nemati

##### Street address

Opposite of 17 Shahrivar Hospital, Shahid Siadati Ave,  
Namjo Ave, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

4144666949

##### Phone

+98 13 3333 5821

##### Fax

+98 13 3333 6395

##### Email

nemati@gums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Rasht University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Zahra Aghaee Kenari

##### Position

MSc Student of Health Education and promotion

##### Latest degree

Bachelor

##### Other areas of specialty/work

Family Health

##### Street address

School of Health, Resalat street, Rasht

##### City

Rasht

##### Province

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418879755

##### Phone

+98 13 3332 3538

##### Email

aghaeezahra@gums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Dr Parisa Kasmaee

##### Position

Associate Professor of Health  
Education and promotion

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

##### Street address

School of Health, Resalat street, Rasht

##### City

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##### Province

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aghaeezahra@gums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Zahra Aghaee Kenari  
**Position**  
MSc Student of Health Education and promotion  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Family Health  
**Street address**  
School of Health, Resalat street, Rasht  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4188794755

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available